

**UNITED STATES DEPARTMENT OF AGRICULTURE**  
**FOOD SAFETY AND INSPECTION SERVICE**  
WASHINGTON, DC

<h1>FSIS NOTICE</h1>	73-05	11/10/05
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**NATIONWIDE RAW GROUND BEEF COMPONENT MICROBIOLOGICAL BASELINE  
DATA COLLECTION PROGRAM – UPDATE**

**NOTE: This notice only applies to inspection program personnel at the establishments that are included as part of the baseline data collection program.**

**I. PURPOSE**

A. This notice announces that the Food Safety and Inspection Service's (FSIS) Nationwide Microbiological Baseline Data Collection Program for Domestic Beef Trimmings will begin on November 28, 2005, and that the 90-day training ("shakedown") period referred to in FSIS Notice 48-05 has ended. The information in the previously-issued Computer Based Training (CBT) compact disc (CD) still applies to this continued sampling program. This notice applies to all samples labeled "MM45" or "MM45R" in block 14 of FSIS Form 10,210-3, Sample Request Form. Additionally, this notice cancels FSIS Notice 48-05.

B. This notice also announces an important change in procedure from the training period. All samples are to be collected and shipped to the laboratories on the day the trimmings are produced (see Section III. B).

**II. BACKGROUND**

A. Inspection program personnel will sample beef trimmings that are available for the production of raw ground beef as part of this baseline study. The sampling will be conducted at approximately 250 establishments that slaughter and fabricate carcasses into trim. This beef trimmings baseline study will not include head meat, organ meat, or advanced meat recovery product (these may be included in a separate baseline program), nor trimmings that are predominantly fat and are most likely destined for such products as finely textured beef or partially defatted chopped beef. In addition, both custom and retail exempt products are excluded from sampling. The term "beef trimmings" includes trimmings from subprimal cuts such as boneless chuck or parts of boneless chuck that are frequently used as components of raw ground beef.

<b>DISTRIBUTION:</b> Establishments Included in Baseline Study, OFO/OAA; OPHS Directors; TSC	<b>NOTICE EXPIRES:</b> 12/1/06	<b>OPI:</b> OPPED
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B. During the 90-day training period, FSIS did not test for any pathogens of public health concern that would render the product adulterated as defined by the Federal Meat Inspection Act (FMIA). During the baseline study, which will continue for a minimum of twelve months, testing will include both regulatory testing for *Escherichia coli* O157:H7 (*E. coli* O157:H7) and non-regulatory testing for other microorganisms. The results will be published as the official baseline report. Inspection program personnel will receive sampling forms and supplies for each requested sample.

### **III. REVIEW OF TRAINING MATERIALS BY INSPECTION PROGRAM PERSONNEL**

A. Inspection program personnel that will be collecting the samples are to complete the training on the CBT CD if they have not already done so. FSIS personnel having questions concerning the training material or the sampling procedures may send the questions to the "Baseline Study Questions" mailbox via e-mail.

B. There is, however, one major difference for the actual baseline program. During the training period, inspection program personnel were instructed to collect samples after any establishment testing for *E. coli* O157:H7 had been completed and the establishment had a negative test result. For the actual baseline, all samples need to be collected and shipped on the day the beef trimmings are produced. This is a change from the CBT CD as to when the samples are to be submitted to the laboratories. However, this is not a change in how the samples are to be collected, or how the samples are prepared for shipment to the laboratories. Inspection program personnel are to continue to follow the instructions in the training CBT for how to prepare the samples for shipment to the laboratories.

### **IV. AWARENESS MEETING WITH PLANT MANAGEMENT**

A. Upon receipt of this notice, the Inspector-in-Charge (IIC) is to have an awareness meeting with plant management to inform them that the baseline study will begin on November 28, 2005. The informational flyer included with the sampling supplies must be provided to the establishment at this time (See Attachment 2).

B. The IIC should emphasize to plant management that the raw beef trimmings sampled will be tested for *E. coli* O157:H7. Inspection program personnel are to inform the establishment that confirmed positive results from testing for *E. coli* O157:H7 may result in regulatory enforcement action under 9 CFR part 500. At a minimum, the discussion should encompass the following:

1. that the establishment is responsible for determining the amount of product represented by the sample (i.e., sampled lot);
2. what product may be implicated based upon the selected sample test results;
3. the in-house controls and microbiological testing concerning organisms of public health concern;

4. that FSIS will recommend a recall in the event an adulterant is found in the product and the product represented by the sample has not been held by the establishment; and

5. that the Agency expects each establishment to carry out any sampling described in its food safety system for raw beef trimmings regardless of whether FSIS collects a baseline sample.

**NOTE:** Inspection program personnel and the establishment should read and become familiar with this notice, as well as FSIS [Directive 10,010.1, Rev. 1](#) and the Questions and Answers on FSIS Directive 10,010.1, Rev. 1, relative to defining lots of affected products based upon microbiological testing under the baseline study and to the amount of notification time prior to sample collection that inspection program personnel should provide the establishment. In addition, industry guidelines may be available for specific production and lotting procedures.

C. Inspection program personnel are to document the meeting in a memorandum of interview. At a minimum, the memorandum of interview will include a list of participants in the meeting and all matters discussed between inspection program personnel and the establishment. The memorandum of interview is to be kept in the inspection files.

## V. OVERVIEW OF SAMPLING PROCEDURES

A. For the baseline study, the sample collection method in the CBT CD supercedes the sample collection instruction in FSIS Directive 10,010.1, Rev. 1. Inspection program personnel will follow the methodology for collecting the samples as shown in the CBT CD.

B. The sampling forms will be marked with either “MM45” or “MM45R” in block 14 of FSIS Form 10,210-3. Each MM45 sample request form and MM45R sample request form identifies the week in which samples are to be collected (Block 4). To the extent possible, all samples should be collected during the designated week. This will help ensure a consistent level of samples throughout the calendar year. If, however, resources (supplies, time or personnel) or trim production timing become an issue, **the laboratories will accept samples collected outside of the designated week.**

C. Sample request forms (MM45 **and** MM45R) that have the same week of collection represent companion samples that form a sample pair. Both halves of the sample pair (MM45 **and** MM45R) need to be collected and shipped at the same time as detailed in the CBT CD **to insure that the results from the sample pair are accepted into the Trim Baseline project database.** MM45 samples are to be shipped to the laboratory contracted by FSIS to conduct the non-regulatory testing [Food Safety Net Services LTD, 221 West Rhapsody, San Antonio, TX 78216]. MM45R samples will be tested for *E. coli* O157:H7 at the FSIS Field Service Laboratories. The MM45R sample **must** be shipped to the laboratory listed in Block 9. If any samples test positive for *E. coli* O157:H7, all product represented by the sample will be considered adulterated.

D. FSIS Notice 48-05 stated that all beef trim baseline samples needed to be collected and shipped on the same day. That will remain the same.

E. On or before the day samples are to be collected, inspection program personnel are to notify the establishment to make sure the establishment has an opportunity to hold all product represented by the sample. Inspection program personnel are to allow the establishment to conduct any lotting or sorting procedures that identify product that is intended for use in raw ground beef versus product that is intended for use in products that will receive a lethality treatment.

F. After notifying the establishment and after the establishment has completed any existing process for sorting the beef trimmings into lots, inspection program personnel are to randomly select a lot to be sampled from the day's production in time to both collect and ship the sample. All samples for the baseline should be collected from lots that are "intended for use in raw ground beef." Product intended for use in raw ground beef includes both:

1. beef trimmings that are currently available for use in raw ground beef and are not subject to any further intervention or testing that is part of the establishment's HACCP system, or

2. beef trimmings that will be released for use in raw ground beef pending a negative result for *E. coli* O157:H7 from a testing program that is part of the establishment's HACCP system.

**REMINDER:** Inspection program personnel are not to collect samples from product that is clearly identified or labeled for use only for further processing where a lethality step will be delivered. Samples can be collected from beef trimmings that are intended to be ground at the establishment or trimmings that will be shipped to be ground at another establishment.

G. Inspection program personnel are to collect two companion samples, **a sample pair**, as per the CBT CD; 120 total pieces emphasizing **carcass surface tissue** where possible. The samples are packed in two boxes as per the CBT CD for mailing to the laboratories. The only change is that the companion samples are to be **collected and shipped on the day they are produced.**

H. If the establishment's food safety system includes a program for testing beef trimmings intended for use in raw ground beef, the baseline sample can be collected before or after the establishment collects its sample.

I. If a shipped sample is from a lot that was tested for *E. coli* O157:H7 by the establishment before that lot was approved for use in raw ground beef and the test result is positive, inspection program personnel are to send an e-mail message to the Outlook address "Trim Baseline In-plant Results." The information in the e-mail is to contain the following:

1. the establishment name;
2. the establishment plant number;
3. the sampled lot number or lot identification;
4. the FSIS sample form numbers that correspond with the sampled lot; and
5. a statement that the establishment's food safety system has found the lot that was sampled to be positive for *E. coli* O157:H7 and the product was diverted and no longer eligible for ground beef.

## **VI. OBTAINING RESULTS OF FSIS MICROBIOLOGICAL TESTING OF RAW BEEF TRIMMINGS**

A. Inspection program personnel are to follow the instructions in FSIS Directive 10,200.1, Accessing Laboratory Sample Information via LEARN, to receive results of regulatory samples tested for *E. coli* O157:H7 (i.e., Project MM45R) during the study period.

B. Inspection program personnel will not receive laboratory testing results for the non-regulatory MM45 samples analyzed at the contracted laboratory. These non-regulatory testing results will also not be posted in LEARN.

## **VII. PRESUMPTIVE POSITIVE OR POSITIVE TEST RESULTS OF RAW BEEF TRIMMINGS**

If test results of raw beef trimmings sampling are either presumptive positive or confirmed positive for *E. coli* O157:H7, inspection program personnel are to follow the instructions found in FSIS Directive 10,010.1, Rev.1. These directions include the notification and reporting procedures for information collected pertaining to the sampled lot. These actions are to be taken by inspection program personnel regardless of whether the results are from establishment testing or FSIS testing.

## **VIII. CLARIFICATION OF COMMON QUESTIONS**

During the 90-day training phase for this baseline study, many questions were fielded at the Technical Service Center and through the "Baseline Study Questions" mailbox in Outlook. Some of these questions are addressed in Attachment 1, "*Consolidated Questions and Answers Concerning Nationwide Microbiological Baseline Data Collection Program for Domestic Beef Trimmings.*"



Assistant Administrator

**Attachment 1**

**Consolidated Questions and Answers Concerning  
Nationwide Microbiological Baseline Data Collection Program for  
Domestic Beef Trimmings**

**Supplies and Shipping Procedures**

**1. Question:**

*The Computer-Based Training (CBT) CD mentions that a fuchsia (bright pink) sticker identifying the samples for this baseline study should be affixed to the shipping container. What do inspection program personnel do when this sticker is missing?*

**Answer:**

Initially, the sticker included with supplies for this study was white due to a shortage in fuchsia (bright pink) stickers. Fuchsia (bright pink) stickers are now available and should be included with supplies (or already affixed to the shipping box). These stickers identify the box as containing samples for this baseline study. Be sure the shipping box has a fuchsia (bright pink) label affixed before it is shipped.

**2. Question:**

*What do inspection program personnel do if they receive two sample request forms, but only one set of collection and shipping supplies?*

**Answer:**

Please check the sample collection form for the date(s) of collection. Once the 90-day training ("shakedown") period is over, sample collection will require two sets of sampling supplies -- one for the MM45 sample and one for the MM45R sample. Shipping boxes containing supplies will be mailed one week before the scheduled date of collection. If, on the Thursday or Friday before the week of collection, all supplies have not arrived, please send an e-mail to the "Sampling Supplies" mailbox for the FSIS laboratory listed in Block 9 on the sample collection form for the MM45R sample.

**3. Question:**

*What do inspection program personnel do if supplies do not arrive before the scheduled sample collection date?*

**Answer:**

Please wait for sampling supplies to arrive in order to take a sample. The laboratories will accept samples collected outside of the designated sample collection week. If supplies have not arrived 21 days after the scheduled date listed in block 4 of the sample request form, please complete block 33 of the form with (67) checked. The form should then be mailed to the laboratory identified in block 9.

4. Question:

*Can samples be sent to either the contract lab or the FSIS lab on Friday for delivery on Saturday?*

Answer:

Yes, the contract laboratory and the FSIS laboratories are able to receive samples on Saturday. Normal procedures should be followed for submitting official samples to the laboratory on Friday for delivery on Saturdays. Inspection program personnel are to apply the "Saturday Delivery" pressure-sensitive sticker to the sample box and check the "Saturday Delivery" box (Section 6 Special Delivery) on the air bill before submitting a sample to the laboratory in these cases.

**Plant and Product Eligibility**

5. Question:

*What are the criteria for establishments being included in the baseline study?*

Answer:

The establishments:

- a. slaughter more than 100 cattle in a fiscal year under federal inspection;
- and
- b. produce raw beef trimmings from the cattle slaughtered at the federally inspected establishment and sell these trimmings to another federally-inspected establishment for grinding;
- or
- c. produce raw beef trimmings from the cattle slaughtered at the federally-establishment and grind the trimmings in-plant.

**NOTE:** Beef slaughtered under either custom exemptions or retail exemptions are not included in this study. These exempted cattle are also not to be counted toward the 100 cattle stipulation cited above. These exemptions can be found in 9 CFR 303.1.

6. Question:

*What should be done if the plant from which a sample is requested is not eligible for the baseline study?*

Answer:

Block 33 of the sample request form (FSIS Form 10,210-3) should be completed with (60) checked. The form should then be mailed to the laboratory identified in block 9. Additionally, an e-mail should be sent to the "Baseline Study Questions" mailbox through Outlook.

7. Question:

*Are trimmings used to prepare hamburger and beef patties supposed to be sampled too?*

Answer:

Yes. Trimmings used for the production of raw hamburger and/or beef patties are subject to baseline testing.

**Computer-Based Training (CBT) CD**

8. Question:

*What should inspection program personnel do if they cannot get the CBT CD to run correctly?*

Answer:

There have been issues with the performance of the CD if all of the updates available through FAIM have not been installed; particularly FLASH 7 software. If there are issues with the CD not working, inspection program personnel are to contact the FAIM helpdesk ((800)-473-9135). If FAIM helpdesk personnel are unable to resolve the problem, then inspection program personnel are to send an e-mail to the "Baseline Study Questions" mailbox through Outlook explaining the exact issues encountered.

**Administrative**

9. Question:

*What procedure code should be used for collecting samples in the PBIS system?*

Answer:

The code to be used is the 05B02 procedure code. This procedure should be written in as an unscheduled procedure on the day that sample collection occurs.

10. Question:

*When should inspection program personnel notify the plant that samples will be collected for the baseline study?*

Answer:

The establishment must have enough notice to hold all product in the sampled lot, if they so desire.

**Sample Collection**

11. Question:

*Should samples only be collected after the establishment's tests for *Escherichia coli* O157:H7 are confirmed negative?*

Answer:

No. Inspection program personnel are now instructed to collect and ship samples to the contract/FSIS labs prior to receiving results of establishment testing for *Escherichia coli*



O157:H7. This change will not affect FSIS' ability to take enforcement actions regarding regulatory samples. Samples are to be shipped the same day as they are collected.

12. Question:

*Should samples be collected prior to the product leaving the plant if the trimmings are being tested by the establishment for E. coli O157:H7 and the results of the plant's tests aren't known?*

Answer:

**For this study only**, inspection program personnel should collect and ship the samples to the contract/FSIS laboratories prior to the product leaving the plant, regardless of the guidance in FSIS Directive 10,010.1, Rev.1 pertaining to collection, submission and shipping of samples in these circumstances.

13. Question:

Can the samples be collected prior to the pre-shipment review being completed?

Answer:

Samples can be collected prior to the pre-shipment review being completed.

## Attachment 2

### **Notice to Give Plant Management When Certain Regulatory Samples are Taken as Part of FSIS' Nationwide Microbiological Baseline Data Collection Program for Domestic Beef Trimmings**

To: Establishment Manager

FSIS is conducting a national microbial baseline study of beef trimmings and subprimals available for use in raw ground beef production. The inspector will be taking a sample of your beef trimmings that will be analyzed for various micro-organisms including *Escherichia coli* O157:H7. Beef manufacturing trimmings and subprimals contaminated with *E. coli* O157:H7 are adulterated if they are intended to be used in non-intact product such as raw ground beef (see Directive 10,010.1, Revision 1). Any adulterated product shipped in commerce would be subject to recall.

To protect public health and to avoid the negative impact of a recall, FSIS strongly recommends that you hold all product represented by the sample until results are obtained.

Most negative results will be available within 2 days; confirmed positive results may take up to 8 days. Results will be provided to you by the inspector or the District Office. For results of future samples, you can receive results by e-mail (contact your IIC to have an e-mail address added via PBIS).

If a recall is needed, FSIS expects you to initiate the recall in a timely fashion—usually the same day. See FSIS Directive 8080.1 for further details.

It is your responsibility to determine the amount of product represented by the sample. As part of this baseline study FSIS has distributed guidance for determining the product represented by a sample of beef trimmings and subprimals. See FSIS Directive 10,010.1 for additional guidance.

If a test result is positive for *E. coli* O157:H7, and you have distributed the product, FSIS will request that you conduct a recall. The determination of what product is represented by a positive sample will be based on the data generated by your food safety system. In making this determination, FSIS will consider such factors as your coding of product; processing and packaging; equipment; your testing under your HACCP plan; your HACCP plan monitoring and verification activities performed in accordance with 417.2 and 417.4; Sanitation SOP records as required in 416.16; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.